

AMENDED IN ASSEMBLY JANUARY 24, 2000

AMENDED IN ASSEMBLY MARCH 18, 1999

CALIFORNIA LEGISLATURE—1999–2000 REGULAR SESSION

ASSEMBLY BILL

No. 256

Introduced by Assembly Member Zettel

February 1, 1999

An act to add Section 1209.2 to the Business and Professions Code, relating to waived laboratory directors.

LEGISLATIVE COUNSEL'S DIGEST

AB 256, as amended, Zettel. Waived laboratory directors.

Existing law regulating clinical laboratory technology defines a “laboratory director” as any person who is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory as specified, and who substantially meets the laboratory director qualifications under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) for the type and complexity of tests being offered by the laboratory. A violation of the provisions relating to clinical laboratories is a misdemeanor.

The CLIA also provides that a laboratory that performs certain examinations and procedures may apply for a waiver from specified requirements of the CLIA.

This bill would authorize the laboratory director of a registered laboratory performing only tests classified as waived under CLIA to delegate the responsibility for—~~quality~~ *technical and scientific* oversight of the laboratory to a

technical consultant who meets specified criteria. *Under this bill, if the laboratory director delegates the performance of his or her responsibilities, he or she would remain responsible for ensuring that all duties are properly performed.* The bill would also set forth the responsibilities of a technical consultant of the waived laboratory.

Because a violation of these provisions would be a misdemeanor, the bill would create a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1209.2 is added to the Business
2 and Professions Code, to read:

3 1209.2. (a) The laboratory director of a registered
4 laboratory performing only tests classified as waived
5 under CLIA may delegate the responsibility for—~~quality~~
6 *technical and scientific* oversight of the laboratory to a
7 technical consultant. *If the laboratory director delegates*
8 *the performance of his or her responsibilities, he or she*
9 *remains responsible for ensuring that all duties are*
10 *properly performed.* A person acting as a technical
11 consultant of a laboratory performing only tests classified
12 as waived shall meet the following minimum criteria:

13 (1) He or she shall be a health care professional
14 licensed pursuant to this division who is also a person
15 described in subdivision (a) of Section 1206.5.

16 (2) He or she shall hold a baccalaureate degree in a
17 chemical or biological science or nursing from an
18 institution accredited by the Western Association of
19 Schools and Colleges or an essentially equivalent
20 accrediting agency.

(3) He or she shall have at least one year of training or experience or a combination of both training and experience in clinical laboratory testing.

(4) He or she shall demonstrate competency to serve as a technical consultant to the laboratory director.

For purposes of this section, experience in clinical laboratory testing shall mean that the person has performed the laboratory test or tests that he or she will oversee as a technical consultant as a regular, usual, and customary part of his or her employment.

(b) A technical consultant of a laboratory performing only tests classified as waived under CLIA shall have the following responsibilities:

(1) He or she shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation.

(2) He or she shall be responsible for all of the following:

(A) Selection of test methodology appropriate for the clinical use of the test results, in consultation with the laboratory director.

(B) Establishing a quality control program appropriate for the testing performed, following the test manufacturer's parameters for acceptable levels of analytical performance, and ensuring that these performance levels are maintained throughout the entire testing process from the initial receipt of the specimen through sample analysis and reporting of test results.

(C) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the ~~the—manufacturer's~~ *manufacturer's* established performance specifications.

(D) Ensuring patient test results are not reported until all corrective actions have been taken and the test system is performing properly.

(E) Identifying training needs and ensuring that each individual performing tests receives regular in-service training and education appropriate for performing tests classified as waived under the CLIA.

(F) Evaluating the competency of all testing personnel and ensuring that the staff members maintain

1 their competency to perform test procedures and report
2 the results promptly, accurately, and proficiently. The
3 procedures for evaluation of the competency of the staff
4 shall include, but not be limited to:

5 (i) Direct observations of routine test performance,
6 including patient preparation, specimen handling,
7 processing, and testing.

8 (ii) Monitoring the recording and reporting of test
9 results.

10 (iii) Review of quality control records and preventive
11 maintenance records.

12 (iv) *Direct observations of performance of instrument*
13 *maintenance and functions checks.*

14 (v) *Assessment of problem-solving skills.*

15 (G) *Evaluating and documenting the performance of*
16 *any individual responsible for waived testing at least*
17 *semi-annually during the first year that the individual*
18 *tests patient specimens. Thereafter, evaluations shall be*
19 *performed at least annually unless test methodology or*
20 *instrumentation changes. In that case, prior to reporting*
21 *the results of the tests, the individual's performance shall*
22 *be reevaluated to test his or her use of the new*
23 *methodology or test instrumentation.*

24 SEC. 2. No reimbursement is required by this act
25 pursuant to Section 6 of Article XIII B of the California
26 Constitution because the only costs that may be incurred
27 by a local agency or school district will be incurred
28 because this act creates a new crime or infraction,
29 eliminates a crime or infraction, or changes the penalty
30 for a crime or infraction, within the meaning of Section
31 17556 of the Government Code, or changes the definition
32 of a crime within the meaning of Section 6 of Article
33 XIII B of the California Constitution.